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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,250	02/28/2002	Paul D. Rubin	4821-469	4257
20582	7590	04/01/2005	EXAMINER	
JONES DAY 51 Louisiana Avenue, N.W. WASHINGTON, DC 20001-2113				HAGHIGHATIAN, MINA
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/084,250	RUBIN, PAUL D.
	<b>Examiner</b>	<b>Art Unit</b>
	Mina Haghigian	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 December 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-16, 30-41 and 50-66 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 12-16, 30-41, 50-66 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

Receipt is acknowledged of the remarks filed on 12/01/04. Accordingly claims 12-16, 30-41 and 50-66 are still pending.

Applicant's arguments with respect to the rejection of claim(s) under 35 U.S.C. 112, first paragraph are persuasive and thus the said rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-16, 30-41, 50-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoh (5,120,758) in view of Aslanian (5,990,147).

Satoh teaches pharmaceutical formulations comprising an effective amount of a lipoxygenase inhibitor either alone or in combination with another therapeutic agent selected from anti-inflammatory, antihistamines, etc (col. 13, lines 13-21). Examples of antihistaminic agents include astemizole (col. 13, lines 36-37). Satoh also discloses that the invention relates to a method of inhibiting 5-lipoxygenase activity in mammals including man, and of treating diseases and conditions responsive thereto, particularly inflammatory and allergic disorders, such as allergic rhinitis (col. 13, lines 49-63). Satoh while disclosing class of antihistamines, lacks specific disclosure on norastemizole.

Aslanian teaches formulations comprising a combination of a phenyl-alkyl-imidazole with an H<sub>3</sub> antagonist and a method for treatment of upper airway allergic

responses comprising administering a compound, or salt or solvate thereof of formula I in combination with a histamine H<sub>1</sub> receptor antagonist (col. 3, lines 31-58).

Aslanina teaches that examples of suitable histamine receptor agents include astemizole, norastemizole, etc (col. 4, lines 41-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Satoh on formulations comprising a leukotriene and a second active agent such as an antihistamine, including astemizole to have looked in the art for other specific antihistamines, as disclosed by Aslanian, with the reasonable expectations of successfully preparing formulations that effectively treats allergic conditions such as allergic rhinitis.

Furthermore, It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two known anti-allergic agents. It would follow that the recited claims define prima facie obvious subject matter.

***Response to Arguments***

Applicant's arguments, filed 12/01/04, with respect to the rejection of claim(s) under Satoh in view of Aslanian have been fully considered but they are not persuasive.

Applicant argues that Satoh discloses a genus of compounds that can be used as 5-lipoxygenase inhibitors and other active agents. Applicant believes that "Satoh does not place any limits as to what another therapeutic agent may be". Applicant also states that "There is no teaching or suggestion whatsoever in Satoh as to whether any specific antihistaminic agent would be particularly desirable when in combination with 5-lipoxygenase inhibitors to which it is directed". However the arguments are not commensurate with the scope of the claims. 1) Instant claims require a leukotriene inhibitor (claims 12 and its depending claims) such as a 5-lipoxygenase inhibitor (in claims 13 and its depending claims) or a leukotriene receptor antagonist. Satoh discloses leukotriene inhibitors including lipoxygenase inhibitors such as leukotriene receptor antagonist. 2) Instant claims require combining norastemizole with the leukotriene inhibitor. Satoh discloses combination of agents for treating allergic conditions such as rhinitis. The combinations are clearly stated as a lipoxygenase inhibitor with a second active agent including antihistamines such as astemizole. Aslanian discloses that suitable antihistamines for treating allergic disorders includes astemizole and norastemizole. It would have been obvious to one of ordinary skill to add a second anti-allergic medication to a composition that is taught useful for treating allergies. There does not appear to be a need for undue experimentation. It is noted that combining art-recognized active agents to treat art-recognized disorders is obvious to

one of ordinary skill in the art. It is also noted that Satoh was and is used in a 103, an obviousness rejection, and certain amount of picking and choosing amongst the disclosed species is permitted.

It is further noted that the instant specification does not disclose any unexpected result from combining norastemizole with a leukotriene inhibitor. Absent any unexpected results and the criticality of the said specific combination, an obviousness rejection is appropriate.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

  
Mina Haghigatian  
March 30, 2005